DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0385]

Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Using Electronic Means to Distribute Certain Product Information," dated September 2005. The draft guidance explains that persons can distribute certain product information, such as for recalls and drug safety, by electronic means. We encourage the use of electronic communications for conveying all such important product safety information. We are making clear in this draft guidance that manufacturers may disseminate communications by e-mail or other electronic methods.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**], to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

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Submit phone requests to 301–827–3360. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

The timely dissemination of communications about recalls of FDA regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health. We have encouraged manufacturers to provide such information in a timely manner to distributors, doctors, and others. Over the years, we have worked with manufacturers to promote the use of electronic methods of communication and encourage the use of innovative technologies to disseminate safety information, particularly those that provide a public health benefit. We are making clear in the draft guidance that manufacturers may disseminate the communications discussed in §§ 7.49 and 200.5 (21 CFR 7.49 and 200.5) by e-mail or other electronic methods. The draft guidance also applies to those instances, not addressed in any regulation, where we recommend that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public.

The use of e-mail and other electronic communications has dramatically changed how we and the public convey information. Electronic communications have a number of advantages over paper-based communications. They can significantly shorten the time between an event and the public's knowledge of the event. When the event involves product safety, it is even more important that accurate safety information be transmitted rapidly. E-mail and other electronic communications are generally considered more efficient and more timely than regular or traditional mail. These communications involve considerably less cost to the sender than older, more traditional delivery services. Verification of receipt or delivery is less expensive and can be automatically accomplished. Any necessary followup (such as when receipt of the e-mail is not acknowledged) also can be accomplished electronically. If receipt is never acknowledged, the sender can resort to more traditional methods of notification.

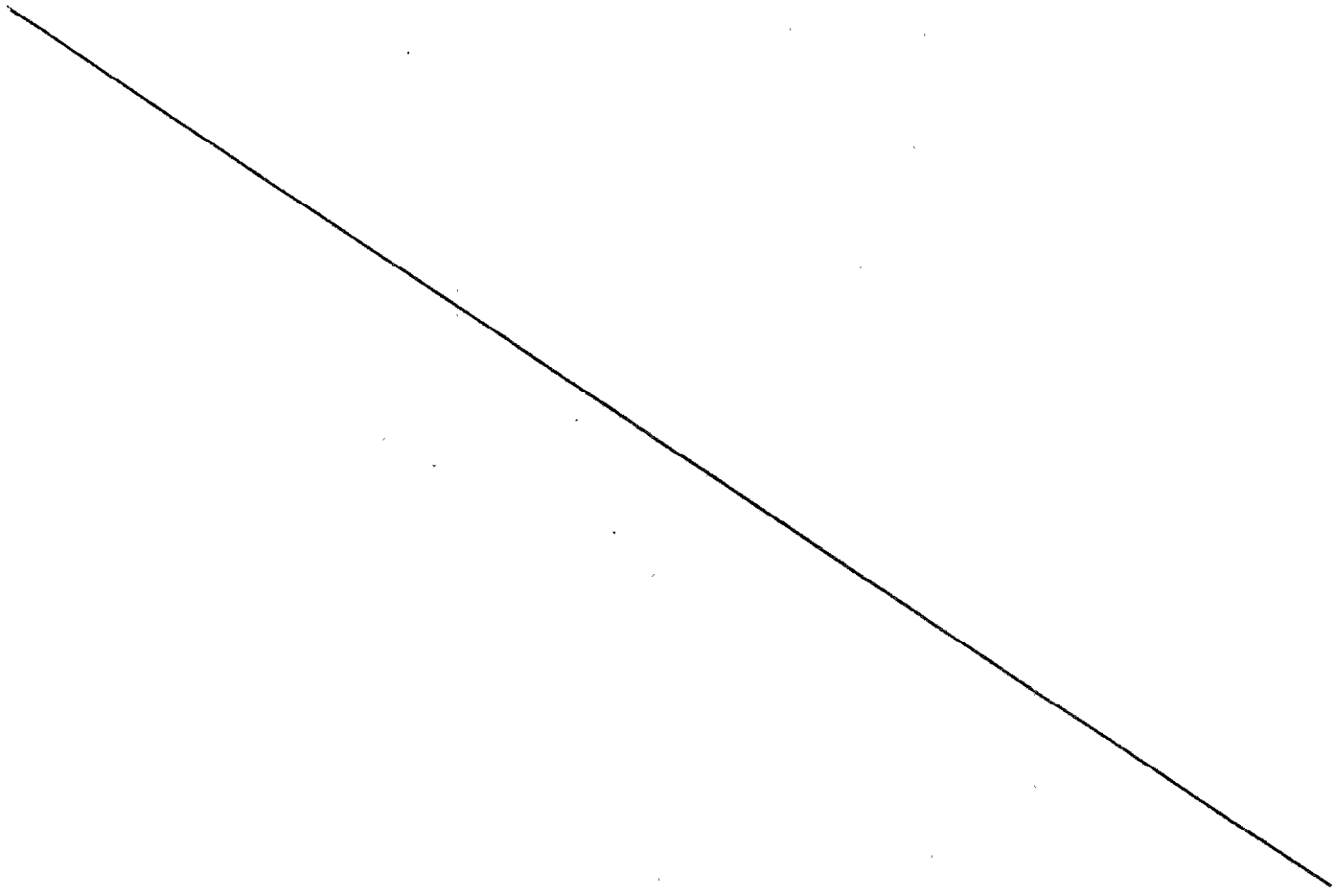
We interpret the provisions of §§ 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information. Section 7.49(b) provides that "A recall communication can be accomplished by telegrams, mailgrams, or first class letters* * *." Given the use of the term "can," we read the three examples as being illustrative rather than the sole means of accomplishing recall communications. Electronic notification is a viable alternative to more traditional methods.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on using electronic means to distribute certain product information. It does not create or confer any rights for or on

any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/guidance/electronic.html* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 9/27/05

September 27, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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